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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,192	12/05/2006	Vega Masignani	PP020009.0003	8434

27476 7590 03/29/2011  
NOVARTIS VACCINES AND DIAGNOSTICS INC.  
INTELLECTUAL PROPERTY- X100B  
P.O. BOX 8097  
Emeryville, CA 94662-8097

EXAMINER
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FORD, VANESSA L

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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03/29/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/552,192

**Applicant(s)**

MASIGNANI, VEGA

**Examiner**

VANESSA L. FORD

**Art Unit**

1645

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2,3,5,6 and 12-27 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 17-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,3,5,6,12-14 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/6/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**FINAL ACTION**

1. Applicant's amendment and response filed January 12, 2011 are acknowledged. Claims 2 and 12 have been amended.

Claims 1, 4, 7-11 and 28 have been canceled.

Claims 15 and 17-27 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 1, 2010.

Claims 2-3, 5-6, 12-14 and 16 are under examination.

2. It should be noted that claim 15 of the amendment filed January 12, 2011 has an incorrect status identifier. Claim 15 should be labeled as (withdrawn).

***Objections/Rejections Withdrawn***

3. In view of Applicant's amendment and response the following rejections have been withdrawn:

- a) objection to claim 7, pages 3-4, paragraph 3.
- b) objection to the specification, pages 4, paragraph 4.
- c) objection to specification, sequence compliance, pages 4-5, paragraph 5.
- d) rejection of claim 2 under 35 U.S.C. 101, page 5, paragraph 6.
- e) rejection of claim 2-3, 5-6, 8-10, 12-14 and 16 under 35 U.S.C. 112 first paragraph (written description), pages 5-9, paragraph 7.

- f) rejection of claim 2-3, 5-6, 8-10, 12-14 and 16 under 35 U.S.C. 112 first paragraph (written description), pages 10-14, paragraph 8.

***Rejection Maintained***

4. The rejection under 35 U.S.C. 102(b) is maintained for claims 2-3, 5-6, 12-14 and 16 for the reasons set forth on pages 4-9 paragraph 4 of the previous Office Action.

The following rejection is maintained and reiterated below:

***Claim Rejection - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claims are rejected under 35 U.S.C. 102(b) as anticipated by Glaser et al (*Science* Vol. 294, October 26, 2001, p. 849-852).

Glaser et al teach a polypeptide that is a functional variant of SEQ ID No.1. Glaser et al teach a polypeptide (lin0059) that is 65.6% identical to SEQ ID NO.1.

Query Match 65.6%; Score 2017; DB 2; Length 577;  
Best Local Similarity 82.3%;  
Matches 408; Conservative 23; Mismatches 35; Indels 30; Gaps 7;

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Qy      1 MKEVNYREDDWREAKSALAPFAAANWVGGLFNNLEKVSKNMEEAEEDVQELDSDHAISFQ 60
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1 MKEVNYREDDWREAKSALAPFAAANWVGGLFNNLEKVSKNMEEAEEDIQELDSDRAISFQ 60

Qy      61 HTNYRGKYSAIEDDLMVLYKFSCHAGEKMETLVDQPFYEKLDAFVDGMQDLSISTYSTTN
120
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      61 HTNYRGKYSAIEDDLMVLYKFSCHAGEKMETLVDQPFYEKLDAFVDGMQDLSISTYSTTN
120
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Glaser et al anticipate the claimed invention.

Applicants Arguments:

Applicant urges that the limitations of claim 7, which was not subject to the rejection, have been incorporated into claim 2. Applicant urges that the claims are not anticipated by Glaser.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed January 12, 2011 have been fully considered but they are not persuasive.

Claim 2 is drawn to an isolated protein consisting of the amino acids sequence of SEQ ID NO.1, with one or more mutations that reduce or eliminate ADP-ribosylating activity of the protein wherein the one or more mutations are made at least one of the following amino acid residues of SEQ ID NO: 504, 506, 537, 539, 548, 564, 567, 570, 573, 574 and 576.

The claims encompasses one or more mutations in the claimed isolated protein. Glaser et al read on the claimed invention because Glaser et al teach a protein that has one or more mutations, does not have ADP-ribosylating activity and has amino acid residues of SEQ ID NO: 504, 506, 537, 539, 548, 564, 567, 570, 573, 574 and 576 deleted.

***Status of Claims***

5. No claims allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANESSA L. FORD whose telephone number is (571)272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571.272.0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/  
Primary Examiner, Art Unit 1645  
March 22, 2011